BEDSIDE DOPPLER IDENTIFICATION OF LOWER-EXTREMITY DEEP-VEIN THROMBOSIS

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1998

Bedside Doppler Identification of Lower-Extremity Deep-Vein Thrombosis

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

by
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1998

Abstract

BEDSIDE DOPPLER IDENTIFICATION OF LOWER-EXTREMITY DEEP-VEIN THROMBOSIS. Gregory S. Raskin and Robert C. Reiser. Section of Emergency Medicine, Department of Surgery, Yale University, School of Medicine, New Haven, CT, and Department of Emergency Medicine, University of Virginia, School of Medicine, Charlottesville, VA.

This study compared the results of handheld Doppler ultrasound performed at the bedside with the results of formal Doppler ultrasound performed in the department of diagnostic imaging for evaluation of deep-vein thrombosis (DVT).

We carried out a prospective 6-month study in an urban teaching hospital emergency department. Patients who were scheduled to undergo formal duplex ultrasound studies to rule out DVT underwent handheld Doppler ultrasound in the Emergency Department (ED) by an ED attending physician or medical student before the formal study, which was conducted in the department of diagnostic imaging. The radiologists were blinded to the results of the ED Doppler examination.

Unilateral duplex ultrasonography and handheld Doppler bedside examination were performed in 30 patients. Four patients were found to have proximal lower-extremity DVT on Doppler ultrasonography, and 26 were found to be free of DVT. Handheld Doppler ultrasound yielded 3 true-positive results, 5 false-positive results, 21 true-negative results, and 1 false-negative result for a sensitivity of 75%, a specificity of 81%, a positive predictive value of 65% and a negative-predictive value of 96%.

Handheld Doppler ultrasound examination in the ED is helpful in the evaluation of patients with suspected lower-extremity DVT. Further study is needed to identify the patients in which this type of examination is not reliable.

Acknowledgments

This thesis was supported by a summer research grant from the Yale School of Medicine Office of Student Research. Travel funding for oral presentation of this subject at the 6th International Conference in Emergency Medicine in November, 1996, was provided by the Section of Emergency Medicine and the Yale School of Medicine Office of Student Affairs.

The author would like to thank Dr. Robert Reiser, without whom this work would have been impossible; and Drs. William Tamborlane and Bernard Lytton, who have served as role models these long Yale years.

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INTRODUCTION

Deep venous thromboses (DVT) account for 600,000 admissions to hospitals per year in the United States.[1] While symptomatic DVT can be uncomfortable and even painful, progression to pulmonary emboli, which have been estimated to account for 200,000 deaths per year in the United States, is the larger concern.[2] Clearly, this is a disease with significant morbidity and mortality. Therefore, it is vital to be able to tell which patients presenting to the Emergency Department (ED) have a DVT, and thus are at risk for a PE.

PATHOPHYSIOLOGY OF VENOUS THROMBOSIS

Lower extremity DVT may occur in the deep veins of the calf, and deep veins above the knee from the popliteal to the femoral system. DVT are made up of fibrin and cellular blood product which is predominately erythrocyte in nature.[3] As pointed out in the 19th century by Rudolph Virchow, three factors predispose to thrombosis: hypercoagulability, venous stasis and endothelial damage. Hypercoagulability can be caused by any number of mechanisms causing coagulation-forming interactions between the extrinsic and extrinsic pathway: surgery, trauma, and burns could all activate the clotting cascade and cause DVT.[3] Venous stasis can be due to immobilization, obstruction, elevated venous pressure due to congestive heart failure, increased blood viscosity and venous dilation. Endothelial damage, caused by trauma such as surgery

completes Virchow's famous triad. [3]

CLINICAL SIGNS AND SYMPTOMS: AN INCONSISTENT PRESENTATION

Despite knowledge of the pathophysiology of DVT, the clinical signs and symptoms historically associated with DVT are unfortunately notoriously unreliable, including pain, swelling, erythema and warmth. In addition, the spectrum of disease for which patients might have such a presentation is likely to include several other, less emergent clinical entities: chronic venous insufficiency, superficial thrombophlebitis, and varicose veins, muscle or soft tissue injury, hematoma, ruptured Baker's cyst, Achilles tendonitis, cellulitis and a number of other syndromes.[4] Due to these two difficulties, some studies have shown that 80% of suspected DVT are negative in ambulatory, non-hospitalized patients.[5]

Indeed, studies which have looked at the clinical presentations of DVT have shown a very mixed picture. One study showed that leg pain is present in only 50% of patients; confusingly, tenderness is absent in up to one-fourth of the patients with DVT -— but present in up to one-half of the patients suspected for DVT but who rule-out.[6] Swelling has been reported as present in up to 80% of patients with DVT.[7]

Coloration of the leg in patients suspected of having DVT can be variable as well. Classically, the leg is thought of as erythematous, from inflammation, venous stasis and engorged blood vessels. However, other coloration is possible. Rarely, cyanosis from extensive iliofemoral venous obstruction can cause the leg to be blue (*phlegmasia cerulea dolens*); similarly, arterial spasm after massive venous obstruction could cause a pale, white

"milk leg" *(phlegmasia alba dolens)*. Fever is commonly associated with DVT, but is also not a failsafe sign.[8]

One method thought to be of value in the clinical diagnosis of DVT was to elicit Homan's sign, calf pain on passive dorsiflexion of the ankle with the leg straight. Unfortunately, this test is neither sensitive nor specific, and may be present in only one-third of patients with DVT. [9, 10]

RISK FACTORS: WHO IS LIKELY TO GET DVT?

Because clinical signs and symptoms cannot be counted on to predict DVT in ambulatory patients, it is important to look to risk factors. Is there a reliable way to know what patient groups are in increased danger of having DVT? Numerous studies have looked at the sorts of patients who get DVT.

There is a long list of risk factors, many of which are controversial. Increased age, obesity, pregnancy, oral contraceptives or estrogens, coagulopathies, trauma, myocardial infarction, congestive heart failure, previous DVT have all been associated with increased risk for DVT.[4] Recent surgery, especially orthopedic procedures, is highly correlated with DVT, with incidences as high as 50% in one study of elective hip surgery.[11]

Cancer also has an association with DVT. Trousseau's syndrome, a paraneoplastic syndrome involving migrating superficial and deep venous thrombosis is often encountered in pancreatic cancer.[4] Malignancy may cause a hypercoagulable state which would make cancer patients more prone to DVT: one study showed a .50 positive predictive value for PE in patients with cancer who underwent arteriography for suspected

PE.[12]

One recent study attempted to quantify the probability of proximal lower extremity DVT by looking at 76 clinical signs, syndromes and risk factors in 355 symptomatic patients who were suspected of having DVT.[8] This study showed that five independent clinical correlates — swelling above the knee of the affected leg, swelling below the knee of the affected leg, recent immobility, cancer and fever — predicted DVT. Patients with none of these five findings had a 5% incidence of DVT; with one risk factor, 15% of patients had DVT; and 42% of patients with two or more risk factors had DVT. This was a retrospective study, and other studies have not specifically confirmed these guidelines. Prospective confirmation is needed before these data can be used as anything more than a helpful guideline.

RADIOGRAPHY AND DVT: A BRIEF GUIDE

Clearly, clinical presentation and risk factor assessment are not sufficient to diagnose DVT. A wide array of radiographic studies has been used to look for DVT. Over the years, venography, impedance plethysmography, Doppler ultrasonography, Duplex ultrasonography, ^{125}I-fibrinogen scanning, and other radioisotope techniques have been used to assess suspected DVT.

Venography, long considered the "gold standard" for assessing DVT in the lower extremity, allows visualization of the entire venous system of the leg, beginning at the common iliac vein. Rabinov and Paulin delineated four criteria for the radiologic diagnosis of DVT by venography: constant filling defects seen in multiple views and which

are sharply demarcated; termination of contrast material at a consistent point; non-filling of the entire deep venous system; and collateral circulation due to a diversion of flow.[13]

When used correctly, the sensitivity and specificity of this test is roughly 100%.[4] Contrast venography, however, brings its own set of problems. First, the test is invasive: it is painful and has even been said to rarely cause thrombosis.[14] Furthermore, inadequate filling results in inconclusive studies in 5% of patients.[4] Overall, studies have shown that up to 25% of patients with suspected DVT may have contraindications or non-diagnostic venograms.[15] Furthermore, a contrast study may be difficult to obtain in community hospitals or during off-hours, and the procedure is expensive.

Despite the accuracy of contrast venography, the limitations caused other methods of diagnosing DVT to be developed. Impedance plethysmography involves temporarily occluding venous flow using a pneumatic pressure cuff applied to the patient's leg and inflated for a set period of time. Changes in the impedance to electrical current correlate with changes in blood volume: higher blood volume reduces impedance. Thus, the cuff is inflated (although not strongly enough to occlude arterial flow) and venous flow is stopped, resulting in increased venous pooling distal to the cuff. When the cuff is released, normal individuals will rebound with rapid venous outflow. In the presence of proximal DVT, that rebound flow will be decreased, as will the initial increase in distal pooling.

Impedance plethysmography is considered both sensitive and specific for proximal lower extremity DVT, and provides noninvasive, immediate information.[15] However, as with venography, impedance plethysmography has several disadvantages. It is not

sensitive for calf DVT, and is also inadequate to distinguish non-occlusive DVT. In addition, there are several clinical scenarios which result in incorrect results, including increased central venous pressure, arterial insufficiency and dressings or casts on the leg.[4]

Doppler ultrasound was first used to look at suspected DVT by Sigel et al in 1968.[16] A 5 MHz probe can be used to detect the speed of moving red blood cells in the deep venous system while the patient is positioned supine with the legs straight. Baseline biphasic venous flow, respiratory variation and calf augmentation can be used to evaluate the possibility of DVT. This noninvasive test has been shown in a meta-analysis of more than 2,000 patients to have a sensitivity of 84% and a specificity of 88% when compared to venography.[17]

Duplex, or B-mode ultrasonography takes the technology of Doppler ultrasound and adds simultaneous real-time imaging of the veins themselves. Color flow Doppler imaging allows the visualization of flow where the color of the stream correlates to the velocity of the signal. The main gauge in Duplex ultrasonography is the compressibility of the veins themselves, which is accomplished with the ultrasound probe; non-compressible veins are suggestive of a thrombus.

The advantages of Duplex ultrasonography are clear, it is noninvasive, sensitive and specific for proximal DVT; it is also useful in assessing superficial thrombophlebitis, cellulitis and Baker's cysts, all of which are on the differential of DVT.[18] A meta-analysis of Duplex ultrasound showed sensitivities ranging from 92% to 95%, with specificities ranging from 97% to 100%.[18] In fact, Duplex ultrasonography is considered by many to be the new "gold standard."

Another, less frequently used test involves radionuclide scanning for DVT with ^{125}Iodine labeled fibrinogen. The test is minimally invasive, and more accurate in detecting calf DVT. Unfortunately, the test is less accurate in picking up proximal DVT, and also carries a small risk of Hepatitis C from the human blood product, although no such transmission has been recorded.[4,19] In general, this test is not as widely used, and should not be used as the only test for patients in the emergency department, as it requires longer than 24 hours for a positive result.[20]

WHEREFORE ART THOU, RADIOLOGIST?

The tests described above have given physicians the ability to detect DVT in patients. Clinicians use their clinical judgment to determine who should go up to the radiology department for further evaluation. Yet a large problem exists with this protocol: in most hospitals around the country, the radiology department is only open during normal business hours. DVT do not wait for business hours to strike, yet 76% of the time — evenings, nights, weekends — there is no radiologist in the hospital. In some cases, a radiologist is on call and may come in from home; however, in smaller communities this is not possible. Furthermore, in isolated areas with public health service hospital coverage, and certainly in developing countries around the world, Duplex ultrasonography and contrast venography are unavailable at any hour.

Statement of Purpose

Because of the urgency and potential danger in DVT, it is essential to diagnose correctly worrisome lower extremities. Previously mentioned problems in hospital coverage by the radiology department point to the utility of an easy test that could be accomplished in the Emergency Department, by an Emergency physician, to rule-out DVT. Handheld Doppler ultrasound, using a state-of-the-art machine to provide a clear audio signal, could be an easy and effective screening method to rule out DVT in Emergency Room populations. We performed our study to examine the feasibility of such a test, and to compare handheld Doppler ultrasound with the gold standard at our hospital, Duplex ultrasonography.

Methods

We studied patients presenting to the Emergency Department (ED) from July 1995 to February 1996 who were suspected of having a lower-extremity deep-vein thrombosis (DVT) and who had already been scheduled to have Duplex ultrasonography performed on the suspect leg. Consent was obtained orally in accordance with Human Investigations Committee Protocol #8239 (See *Appendix 1*).

Inclusion criteria for the study were the following: age greater than 18 years old; and Duplex Ultrasound ordered to rule out lower extremity DVT. There were no exclusion criteria.

A clinical pre-test probability was first estimated by the investigator, taking into account two criteria: risk factors and clinical presentation. The attending physician used both his clinical judgement and Landefeld's criteria (swelling above the knee, swelling below the knee, cancer, fever and recent immobilization) to categorize the patients into low-, intermediate-, and high-risk groups.[8] This clinical categorization was done independently of the DU testing.

Next, handheld Doppler Ultrasonography (HDU) was performed in the Emergency Department using a Multi Dopplex II continuous-wave Doppler Ultrasound device outfitted with a VP5 5MHz transducer head probe (HNE Healthcare, Inc., Manalapan, NJ). The two investigators were the only people to perform the test during the study. The medical student performed 20 of the 30 HDU tests in this study (67%).

The technique employed was a modified version of the one used by Barnes et al[21]. With the audio volume of the MultiDopplex set to the maximum position, the probe was placed at a 45-degree angle to the line of blood flow over the femoral artery of the leg being examined. The high-pitched, pulsatile sound of the femoral artery served as an anatomical landmark, and the probe was then moved medially to the femoral vein. Three measurements were taken, alternation first from the leg not suspected of having DVT, and then to the suspect leg (see Table I for a brief synopsis).

First, baseline biphasic flow in the femoral vein of the non-suspect leg was recorded on a zero to two scale (0, 1+, 2+) where zero represented no flow (*i.e.*, no biphasic audio signal), 1+ represented diminished flow (*i.e.*, diminished biphasic audio signal), and 2+ represented normal flow (*i.e.*, normal, vigorous biphasic audio signal). This measurement was then repeated on the suspect leg.

Next, a study of forced respiratory variation was performed on the non-suspect leg. Forced inspiration tends to increase intra-abdominal pressure and thus decrease venous return, thus decreasing the Doppler signal. Respiratory variation in the femoral vein was recorded on a zero to two scale (0, 1+, 2+) where zero represented no respiratory variation (*i.e.* no decrease in audio signal), 1+ represented diminished respiratory variation (*i.e.*, moderate decrease in audio signal), and 2+ represented normal respiratory variation (*i.e.* marked decrease in audio signal). This measurement was then repeated on the suspect leg.

Finally, calf-compression augmentation was performed on the non-suspect leg. When the calf muscles are compressed by the examiner, venous return tends to increase

as a volume of blood is forced back toward the probe at an increased speed. This correlates to an increase in the velocity signal. Calf-compression augmentation in the femoral vein was recorded on a zero to two scale (0, 1+, 2+) where zero represented no calf-compression augmentation (*i.e.*, no increase in audio signal), 1+ represented calf-compression augmentation (*i.e.*, moderate increase in audio signal), and 2+ represented normal calf-compression augmentation (*i.e.*, marked increase in audio signal). This measurement was then repeated on the suspect leg.

The three measurements in each of the two legs were compared, and deviation from the level of the non-suspect leg by the suspect leg in any of the three measurements was considered a positive test.

After completion of the clinical categorization and the HDU auscultation of the femoral veins, the patient was sent from the Emergency Department to the Radiology Department for Duplex ultrasonography of the affected leg. Duplex ultrasonography included both color Doppler flow measurements in the affected leg, and venous compression by the transducer probe. The Radiology Department was blind to the results of the HDU tests when they performed the Duplex Ultrasonography.

TABLE I	0	1+	2+
Biphasic Flow	no signal	decreased signal	normal signal
Respiratory Variation	no decrease in signal	moderate decrease in signal	marked decrease in signal
Calf-compression Augmentation	no increase in signal	moderate increase in signal	marked increase in signal

A standard 2 x 2 table was used to compare HDU to Duplex Ultrasonography, and classified as true-positive (TP), true-negative (TN), false-positive (FP) or false-negative (FN). Sensitivity (TP/[TP + FN]), specificity (TN/[TN + FP]), positive predictive value (TP/[TP + FP]), and negative predictive value (TN/[TN + FN]).

Statistics were analyzed using EpiInfo version 6 (Centers for Disease Control, Atlanta). The 2 x 2 tables created with the data were subjected to the Fisher exact test due to low expected frequencies.

RESULTS

Thirty patients met inclusion criteria during the eight-month study. All patients had both handheld Doppler ultrasonography in the Emergency Department as well as Duplex ultrasound performed by a radiologist in the Radiology Department.

Eighteen of the patients were women, and 12 were men. The patients had a mean age of 57, with a range from 26 to 80.

Out of the 30 patients tested by our study to rule out DVT, handheld Doppler ultrasound showed 22 negative studies and 8 positive studies; Duplex ultrasonography performed by the Radiology Department resulted in 26 negative studies and 4 positive studies. This data is displayed in *Chart I*.

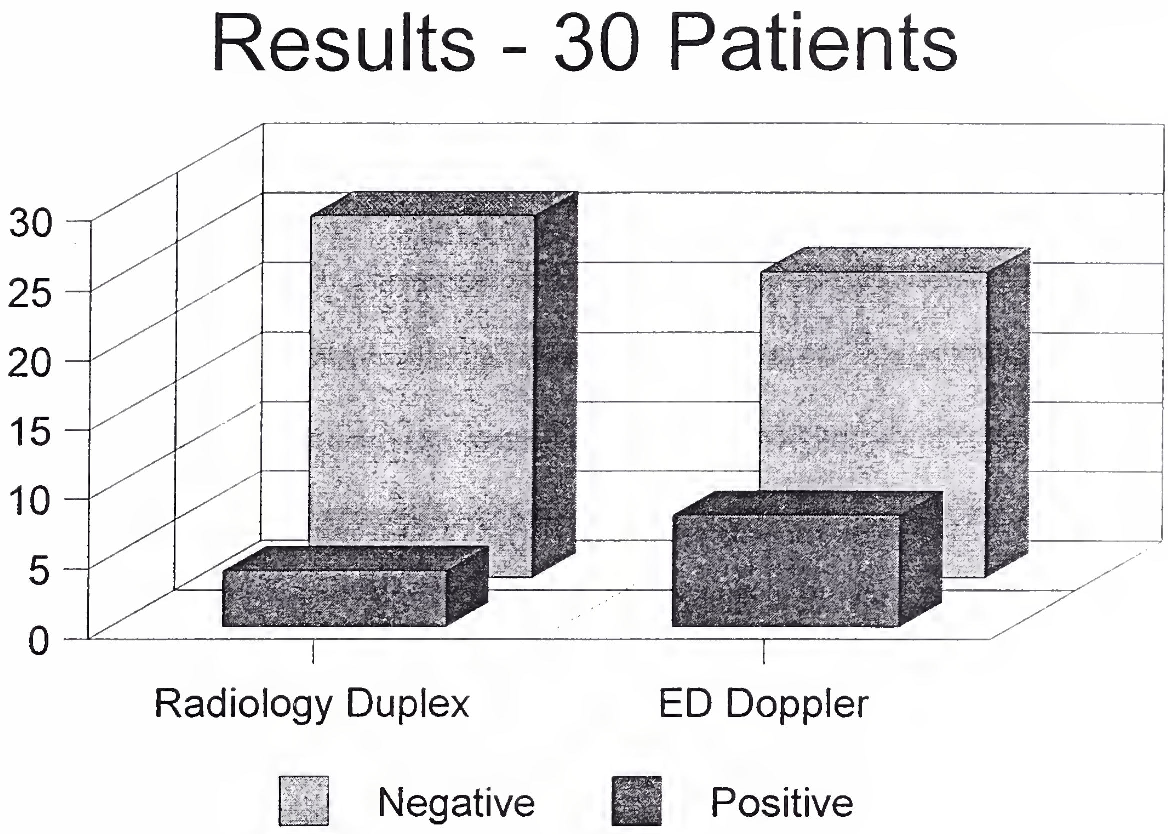

Chart I: Duplex vs. Doppler

Of the 26 studies negative by Duplex ultrasound, 21 were found to be negative by handheld study (21 true-negatives, 5 false-positives). Of the 4 studies which were positive by Duplex ultrasound, 3 were found to be positive by handheld Doppler (3 true-positives, 1 false-negative). This data is shown in *Table II*.

Table II - All patients. (p<.05)

All Patients	Duplex Positive	Duplex Negative
ED Positive	3	5
ED Negative	1	21

The data can be broken down into separate categories, taking into account the pretest clinical assessment by the clinician performing the handheld Doppler ultrasound of low, intermediate or high probability. For low risk patients, there were 9 negative handheld readings, all of which corresponded with Duplex ultrasound (9 true negatives). For intermediate risk patients, handheld Doppler agreed with Duplex on 9 negative studies and two positive ones, while two studies read as positive by handheld Doppler were negative by Duplex (2 true-positives, 9 true negatives, 2 false-positives). Finally, in the high risk category, there was agreement for three negative studies and one positive one, while handheld Doppler found three positive studies which were called negative by Duplex, and called one study negative which was assessed as positive by Duplex (1 true-positive, 3 true-negatives, 3 false-positives and 1 false-negative). See *Tables III, IV, and V.*

Data from all patients yielded an overall sensitivity of 75%, a specificity of 81%, a negative predictive value of 96%, and a positive predictive value of 65% for handheld Doppler ultrasound ($p<.05$ by Fisher's exact test.) However, if the low and intermediate risk groups were treated together (Table VI), separately from the high risk patients, the

sensitivity of the test rose to 100%, the specificity to 90%, the positive predictive value was 50% and the negative predictive value was 100% (p=.03 by Fisher's exact test). Data from high risk patients taken alone yielded a sensitivity of 50%, a specificity of 50%, a positive predictive value of 25%, and a negative predictive value of 75% (p=1.0 by Fisher's exact test, thus data is not significant.) This data is summarized in *Table VII*.

Table III - Subgroup: Low Clinical Risk Patients (p=n/a)

Low Clinical Risk	Duplex Positive	Duplex Negative
ED Positive	0	0
ED Negative	0	9

Table IV - Subgroup: Intermediate Clinical Risk Patients (p=.08)

Intermediate Clinical Risk	Duplex Positive	Duplex Negative
ED Positive	2	2
ED Negative	0	9

Table V - Subgroup: High Clinical Risk Patients (p=1.0)

High Clinical Risk	Duplex Positive	Duplex Negative
ED Positive	1	3
ED Negative	1	3

Table VI - Subgroup: Low and Intermediate Clinical Risk Patients (p=.03)

Combined Low and Intermediate Clinical Risk	Duplex Positive	Duplex Negative
ED Positive	2	2
ED Negative	0	18

Table VII - Summary of Diagnostic Characteristics

	All patients (p<.05)	Combined Low and Intermediate Risk Patients (p=.03)	High Risk Patients (p=1.0)
Sensitivity	75%	100%	50%
Specificity	81%	90%	50%
Positive Predictive Value	96%	50%	25%
Negative Predictive value	65%	100%	75%

Discussion

Since Virchow recognized the association between deep venous thrombosis and pulmonary embolism in 1846, DVT has been seen as a serious and potentially life-threatening problem; diagnosis of DVT before it progresses to pulmonary embolism is vital. Two radiologic tests have long been proven to do this accurately: venography and Duplex ultrasound. However, as mentioned above, these facilities are not always available.

In the emergency department, the ability to determine whether or not a DVT is present in a painful, swollen and/or red leg has long been based on clinical presentation. This information has long been shown to be spurious at best. In studies of clinical data, most symptomatic patients have no DVT.[5] Cranley et al. even argue that clinical data cannot be used to diagnose or rule out DVT.[6] A recent retrospective study by Landefeld looked at clinical features, but did so only retrospectively.[8] Thus, clinical presentation in the emergency department has not been shown to be a reliable predictor of which patients have a DVT.

In hospitals where venography or Duplex ultrasound are always available, patients can be screened without problem or delay. However, in the numerous medical centers where 24-hour radiology coverage is not possible, these patients have to be admitted to the hospital and put on heparin until a radiologic test can be performed. Thus, a test that could reliably rule out DVT in the absence of a radiologist would be an invaluable tool to

emergency physicians around the world.

Doppler ultrasound is noninvasive and does not subject the patient to ionizing radiation. It is also a quick test which can be performed at the bedside in roughly a quarter of an hour. Furthermore, handheld Doppler machines are relatively inexpensive, especially when compared to the cost of a night in the hospital, not to mention the cost of a missed diagnosis. Thus, handheld Doppler ultrasound would seem to offer numerous benefits to the patient.

In order to make the screening test as quick as possible, only the femoral veins were auscultated in our study. Adding the popliteal veins is an additional maneuver which would likely double the time of the test, require the patient to turn over, and increase the difficulty of the test for the examiner. Presumably, blockages lower down in the venous anatomy than the femoral veins would be picked up by the calf-augmentation maneuvers.

While no previous studies have compared handheld Doppler ultrasound to Duplex Ultrasound, three previous studies have looked at Doppler ultrasound in comparison with venography in assessing suspected legs for DVT. [22,23,24] Hanel et al studied 49 symptomatic outpatients and showed a sensitivity of 88%, a specificity of 94%, a negative predictive value of 94% and a positive predictive value of 88% when compared to venography. [23] Stair retrospectively studied 15 patients who had both Doppler ultrasound and venography, and showed a sensitivity of 100%, a specificity of 78%, a negative predictive value of 100% and a positive predictive value of 75% when compared to venography.[24] Finally, Turnbull et al showed that Doppler ultrasonography had a sensitivity of 85%, a

specificity of 79%, a negative predictive value of 92% and a positive predictive value of 65% when compared to venography in 76 patients.[25]

Our data, comparing handheld audio Doppler ultrasound to Duplex ultrasonography, showed an overall sensitivity of 75%, a specificity of 81%, a negative predictive value of 96%, and a positive predictive value of 65% for handheld Doppler ultrasound. However, if the low and intermediate risk groups were treated together, separately from the high risk patients, the sensitivity of the test rose to 100%, the specificity to 90%, the positive predictive value was 50% and the negative predictive value was 100%.

In screening tests, it is generally held that some false-positives can be tolerated as long as there is a low frequency of false-negatives. We had one high-risk patient who turned out to have a false-negative Doppler scan. On Duplex ultrasound, she was shown to have a non-occlusive right common femoral thrombus extending into the right external iliac vein. This points to a possible problem in our test: it may be that non-occlusive thrombi are difficult to assess, as there might not be enough difference in audio signal between veins with non-occlusive thrombi and veins free of any thrombus.

There are several other limitations to our study. First, as with any test, there is the question of intra-observer variability: How reproducible is the data? We attempted to minimize this variability by comparing the two legs against each other during the exam. Using a 0, 1+, 2+ scale, any variation between the two legs is considered a positive result.

Second, the number of patients enrolled in our study was admittedly small:

patients present irregularly to the emergency department with this problem, and despite having 24-hour coverage for much of the study time period, data collection was slow. The incidence of DVT in our population was 13%, which is significantly lower than the estimates of the roughly 20% prevalence of DVT in non-hospitalized, ambulatory patients suspected of having a DVT.[3] To increase the power of the results, it would be necessary to enroll more patients.

Furthermore, there is the problem of distal lower extremity DVT. Small isolated calf vein thrombi are not readily appreciated using handheld Doppler ultrasound. Indeed, the sensitivity of even Duplex ultrasonography is far from satisfactory, as it is difficult to visualize calf veins. The clinical significance of calf thrombi is widely debated, and in cases where calf thrombus is suspected, follow-up noninvasive studies are suggested. [25,26]

In conclusion, we feel that handheld Doppler ultrasound is indeed accurate for ruling out DVT in low and intermediate risk patients in patients for whom gold standard testing is not readily available, as the sensitivity was 100% and the negative predictive value was likewise perfect. Our recommendation would then be to use a negative handheld Doppler reading to rule out DVT in low and intermediate risk patients in patients for whom gold standard testing is not readily available, thus saving these patients a night in the hospital and the risks of heparin. For positive results in low and intermediate risk patients, they should be treated and admitted, and then radiographed using a gold standard test (*i.e.*, Duplex ultrasound or venography) as soon as possible. In high risk populations, however, we feel that there is not enough evidence at this time to support ruling out DVT with handheld audio Doppler ultrasonography, and the patient

must undergo either Duplex ultrasonography or venography.

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APPENDIX 1

Patient Information

Bedside Doppler Identification of
Lower Extremity Deep Venous Thromboses

HIC #8239

You are invited to participate in a research project designed to look for blood clots in your leg using ultrasound.

The Emergency Department physician has ordered an ultrasound study of the blood vessels of your leg(s), because he or she is concerned about the possibility of a blood clot in your leg(s).

While you are in the Emergency Department, we would like to perform an additional ultrasound to supplement the ultrasound you will receive later. This additional test is for research purposes and will not benefit you directly. With your consent, we would like to use the information gathered from this additional ultrasound for a research study designed to improve the care of patients with your condition.

Your participation in this study is voluntary. You are free to refuse to participate or withdraw at any time without affecting your care in any way. There is no charge to you for the additional study.